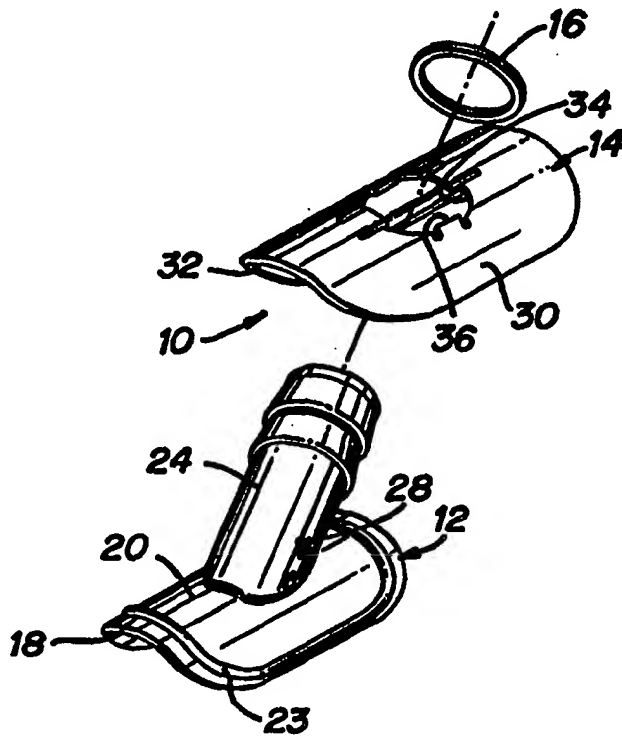


PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/06, A61B 17/11		A1	(11) International Publication Number: WO 98/40036 (43) International Publication Date: 17 September 1998 (17.09.98)
(21) International Application Number: PCT/US98/05031 (22) International Filing Date: 13 March 1998 (13.03.98) (30) Priority Data: 08/816,615 13 March 1997 (13.03.97) US (71) Applicant: UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US). (72) Inventors: MANZO, Scott, E.; 272 East Village Road, Shelton, CT 06484 (US). HINCHLIFFE, Peter, W., J.; 285 Central Avenue, New Haven, CT 06515 (US). SNIFFIN, Kevin; 38 Grand Street, Danbury, CT 06810 (US). (74) Agents: GERSHON, Neil, D. et al.; United States Surgical Corporation, Legal Dept., 150 Glover Avenue, Norwalk, CT 06856 (US).			(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: GRAFT ATTACHMENT ASSEMBLY			
(57) Abstract <p>A graft attachment assembly that may be easily and quickly assembled is provided. The graft attachment assembly includes an attachment member including a base portion having a convex top surface and a branch portion having a passageway therethrough. The branch portion projects outwardly from the base portion. A clamp member having a concave bottom surface is configured to sealingly engage the top surface of the base portion and an opening is dimensioned to slidably receive the branch portion. The clamp member is slidable about the branch portion to a position adjacent the base portion to clamp tissue therebetween. A locking member is slidable about the branch portion and dimensioned to secure a vessel thereabout.</p>			
			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

GRAFT ATTACHMENT ASSEMBLY

BACKGROUND

1. Technical Field

5 The present disclosure relates generally to grafts for surgical use and, more specifically, to a graft attachment assembly which may be easily and quickly assembled. The graft attachment assembly is particularly suited for vascular bypass surgical procedures.

2. Background of Related Art

10 Vascular grafts for use in surgical procedures for bypassing a section of a main artery to prepare the bypassed section of artery for surgical repair are well known and have taken a variety of different forms. Typically, vascular grafts include an inlet conduit to receive blood flow from an arterial source and an outlet conduit to deliver blood flow to a downstream location, e.g., same or different arteries, body organs, etc. A sealing device is positioned adjacent to each inlet and outlet conduit.
15 Because of the nature of bypass procedures, it is important that a vascular graft be implantable in a relatively short period of time and that the vascular graft be properly attached to the vessels and adequately sealed at its inlet and outlet ends.

20 U.S. Patent No. 4,712,551 to Rayhanabad discloses a vascular shunt having a tubular inlet conduit and a plurality of outlet branch portions. The inlet conduit is configured to be received within an upstream arterial lumen and includes a sealing mechanism in the form of an expandable collar. Each outlet branch portion is configured to be received within a downstream arterial lumen and also includes an expandable collar. An air supply source communicates with each collar via an air supply line to inflate the collar and move the inlet conduit and each of the outlet branch
25 portions into sealing engagement with the inner walls of the arterial lumen. Although

the expandable seals are effective, the additional attachments required in the limited confines of a surgical site are undesirable.

U.S. Patent No. 5,156,619 to Ehrenfeld also discloses a vascular graft having a straight portion, and a flange portion including a crotch region. The flange portion is in the shape of a continuous flow curve and includes a suturing surface. The vascular graft is anastomosed to the aorta using hand applied sutures. Ehrenfeld's vascular graft still requires the time consuming and often times difficult process of suturing.

Accordingly, a need exists for an improved vascular graft that can be easily and quickly implanted, provides improved sealing, and can be easily and inexpensively manufactured.

SUMMARY

In accordance with the present disclosure, a graft attachment assembly is provided having an attachment member, a clamp member, and a locking member. The attachment member includes a base portion having a preferably concave top surface and at least one branch portion having a passageway therethrough projecting outwardly from the base portion. The clamp member is preferably formed with a convex bottom surface configured to sealingly engage the top surface of the base portion and has an opening dimensioned to slidably receive the branch portion. The clamp member is movable about the branch portion to a position adjacent the base portion to clamp tissue therebetween. The locking member, preferably a locking ring, is slidable about the branch portion and is dimensioned to secure a vessel thereabout. A sealing assembly, preferably in the form of a rib formed on one of the top and bottom surfaces and a channel aligned with the rib formed in the other of the top and bottom surfaces,

provides a seal between the base portion and the clamp member in the clamped position of the graft attachment assembly. The branch portion, illustratively, has at least one annular ramped surface positioned thereabout which is dimensioned to retain the locking ring in position about the distal end of the branch portion. In a preferred embodiment, the clamp member is formed with at least one flexible retaining member positioned about the opening and the branch portion is formed with at least one row of teeth which is aligned with the at least one retaining member in the clamped position to retain the clamp member in the clamped position adjacent the base portion. The retaining member is selectively movable into engagement with any one of the teeth in the row of teeth to accommodate tissues of different thicknesses. Advantageously, a branch portion of the graft attachment assembly may be attached directly to a body vessel and thus serve as a graft or, the branch portion may be attached to an intermediary graft and serve as an attachment member for a graft.

DETAILED DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view with parts separated of one embodiment of the vascular graft assembly;

FIG. 2 is a side partial cross-sectional view of the vascular graft assembly shown in FIG. 1 in an assembled condition;

FIG. 3 is a cross-sectional view taken along section line 3-3 of FIG. 2;

FIG. 4 is a perspective view of the vascular graft assembly shown in FIG. 1 implanted in the aorta; and

FIG. 5 is a perspective view of an alternate embodiment of the vascular graft assembly.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

5 Preferred embodiments of the presently disclosed graft attachment assembly will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

10 FIGS. 1 illustrates one embodiment of the presently disclosed graft attachment assembly shown generally as 10. Briefly, graft attachment assembly 10 includes an attachment member 12, a clamp member 14, and a locking member 16. Each member of the three part assembly is preferably molded from a biologically compatible material, such as polytetrafluoroethylene, although other suitable methods and materials which meet the requisite requirements for a vascular graft, may also be used. The attachment assembly 10 is utilized to attach a vascular graft or a synthetic
15 graft to a vessel without requiring sutures. Attachment assembly 10 may also be used to attach two body vessels.

Referring also to FIGS. 2 and 3, attachment member 12 is constructed with a base portion 18 having a convex top surface 20 configured to sealingly engage the interior wall of an arterial lumen. An annular rib 23 extends about the periphery of
20 top surface 28. A tubular branch portion 24 defining a cylindrical passageway 21 extends outwardly from top surface 20 and is provided with at least one annular ramped surface 26 and at least one row of vertically aligned teeth 28. Illustratively, branch portion 24 is provided with two spaced annular ramped surfaces and four rows of vertically aligned teeth 28 spaced evenly about the periphery of branch portion 24,

although other configurations may be used. Locking member 16, which is preferably a locking ring, is dimensioned to be slidably received about tubular branch portion 24, and will be described in detail below.

5 Clamp member 14 has a body 30 having a concave bottom surface 32 configured to sealingly engage top surface 20 of base portion 18. An opening 34 dimensioned to receive tubular branch portion 24 of attachment member 12 is formed in body 30. A plurality of diametrically opposed flexible retaining members 36 define a portion of opening 34 and are positioned to engage rows of vertically aligned teeth 28 formed on the outer periphery of tubular branch portion 28. Preferably, a retaining member 36 is provided for each respective row of teeth 28. An annular channel 38 is formed in bottom surface 32 of clamp member 14 and is positioned to receive rib 23 of attachment member 12 when the clamp member 14 is fastened to base member 12 in a clamped position. Referring now to FIGS. 2-4, implantation of graft attachment assembly will now be described, by way of example, for use during a typical bypass procedure. An incision is made in aorta 40 and base portion 18 of attachment member 12 is inserted through the incision. Attachment member 12 is positioned such that branch portion 24 projects through the incision and top surface 20 of base portion 18 is in contact with the inner wall of aorta 40. Clamp member 14 is pressed downwardly onto attachment member 12 by sliding opening 34 of clamp member 14 about branch portion 24 to clamp tissue between bottom surface 32 of clamp member 14 and top surface 20 of base portion 18. Rib 23 forces tissue into channel 38 to provide a seal between clamp member 14 and attachment member 12. Clamp member 14 is retained in a clamped position by retaining members 36 which engage teeth 28. By providing multiple teeth in each row of teeth 28, the location of clamp member 14 with respect to base member 12 may be adjusted to accommodate tissues having different thicknesses.

After attachment member 12 is securely fastened to aorta 40, a vessel 44, e.g., the saphenous vein, may be fastened to branch portion 24 by positioning locking ring 16 about vessel 44, positioning vessel 44 about the distal end of branch portion 24, and sliding locking ring 16 about vessel 44 and branch portion 24 over the distal-most annular ramped surface 26 to a position between ramped surfaces 26. Locking ring 16 is constructed of a resilient material capable of passing over ramped surface 26 and compressing vessel 44 into sealing engagement with branch portion 24. Although branch portion 24 is shown oriented at a forty-five degree angle with respect to the longitudinal axis of attachment member 12, branch portion 24 may be oriented at any angle or direction suitable for the particular bypass application being performed. Moreover, since graft attachment assembly 10 is easily removable, it may be used for permanent or temporary applications.

FIG. 5 illustrates an alternate embodiment of the graft attachment assembly shown generally as 100. Graft attachment assembly 100 includes first, second, and third tubular branch portions 124a, 124b and 124c. Each branch portion has a pair of ramped surfaces 126 and at least one row of vertically aligned teeth 128a, 128b, and 128c. Clamp member 114 has three openings. Each opening is aligned with a respective branch portion and dimensioned to permit passage of the respective branch portion through the opening. Flexible retaining members 136a, 136b, and 136c define a portion of each opening and are engageable with the rows of teeth 128a-c to retain clamp member 114 in a clamped position fastened on attachment member 112. Although not illustrated, a locking member similar to locking ring 16 is associated with each branch portion 124a-c to sealingly fasten vasculature to the distal end of the respective branch portion.

5 It will be understood that various modifications may be made to the embodiments disclosed herein. As is apparent, any number of tubular branches can be provided to extend from graft member 12. Each branch can be placed at not only a 45° or 90° angle as shown, but can be placed at a variety of angles. Moreover, the tubular branches, on each graft member can be placed at different angles. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A graft attachment assembly comprising:
an attachment member including a base portion having a top surface and a branch portion having a passageway therethrough projecting outwardly from the top surface of the base portion; and
5 a clamp member having an opening configured to receive the branch portion, the clamp member being movable about the branch portion, wherein the bottom surface of the clamp member may be positioned adjacent to the top surface of the graft member to clamp tissue therebetween.
- 10 2. A graft attachment assembly according to claim 1, wherein the top surface of the base member is convex and the bottom surface of the clamp member is concave.
3. A graft attachment assembly according to any of the preceding claims, further including a sealing assembly between the top and bottom surfaces.
- 15 4. A graft attachment assembly according to any of the preceding claims, wherein the sealing assembly includes a rib formed on one of the top and bottom surfaces and a channel formed in the other of the top and bottom surfaces, the rib being aligned with the channel in a clamped position.
- 20 5. A graft attachment assembly according to any of the preceding claims, further comprising a locking ring dimensioned to be received about the branch portion to retain tissue thereabout.

6. A graft attachment assembly according to any of the preceding claims, wherein the branch portion includes at least one annular ramped surface positioned thereabout and the locking ring is flexible, the ramped surface being dimensioned to retain the locking ring in position about the branch portion.

5 7. A graft attachment assembly according to any of the preceding claims, wherein the clamp member includes at least one retaining member positioned about the opening and, the branch portion includes at least one tooth which is aligned with the at least one retaining member in a clamped position, wherein the retaining member is movable into engagement with the at least one tooth to retain the clamp member in the clamped position.

10

8. A graft attachment assembly according to any of the preceding claims, wherein the at least one tooth includes a plurality of teeth, the retaining member being selectively movable into engagement with any one of the teeth to accommodate tissues of different thicknesses.

15 9. A graft attachment assembly comprising:
a graft member including a base portion having a top surface and a branch portion having a passageway therethrough, the branch portion projecting outwardly from the base portion;
a clamp member having a bottom surface configured to sealingly engage the top surface of the base portion and an opening dimensioned to slidably receive the branch portion, the clamp member being movable about the branch portion to a position adjacent to the base portion to clamp tissue therebetween; and

20

a locking member slidable about the branch portion, the locking member being dimensioned to secure a vessel about the branch portion.

5 10. A graft attachment assembly according to any of the preceding claims, wherein the top surface of the base member is convex and the bottom surface of the clamp member is concave.

 11. A graft attachment assembly according to any of the preceding claims, further including a sealing assembly between the top and bottom surfaces.

10 12. A graft attachment assembly according to any of the preceding claims, wherein the sealing assembly includes a rib formed on one of the top and bottom surfaces and a channel formed in the other of the top and bottom surfaces, the rib being aligned with the channel in the clamped position.

 13. A graft attachment assembly according to any of the preceding claims, wherein the branch portion includes at least one annular ramped surface positioned thereabout, the ramped surface being dimensioned to retain the locking ring in position about the branch portion.

 14. A graft attachment assembly according to any of the preceding claims, wherein the clamp member includes at least one retaining member positioned about the opening and, the branch portion includes at least tooth which is aligned with the at least one retaining member in the clamped position, wherein the retaining

20

member is movable into engagement with the at least one tooth to retain the clamp member in the clamped position.

5 15. A graft attachment assembly according to any of the preceding claims, wherein the at least one tooth includes a plurality of teeth, the retaining member being selectively movable into engagement with any one of the teeth to accommodate tissues of different thicknesses.

 16. A graft attachment assembly according to any of the preceding claims, wherein the graft assembly is constructed from a biologically compatible material.

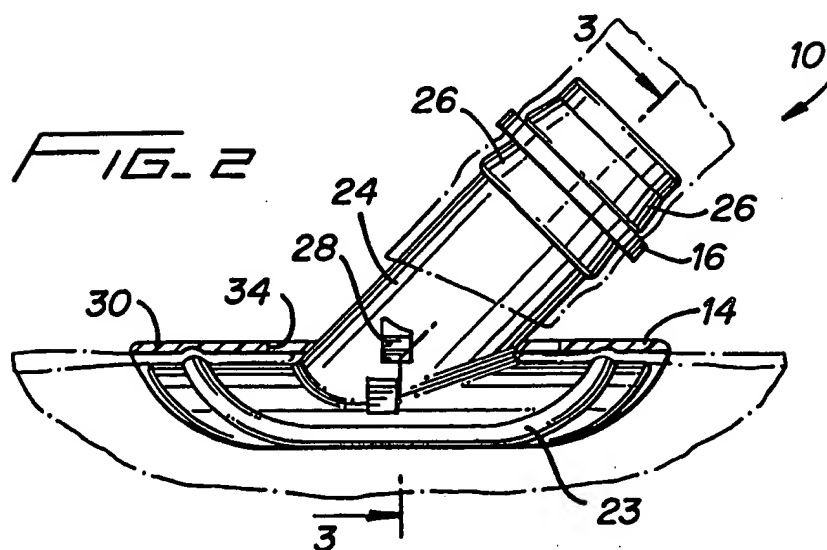
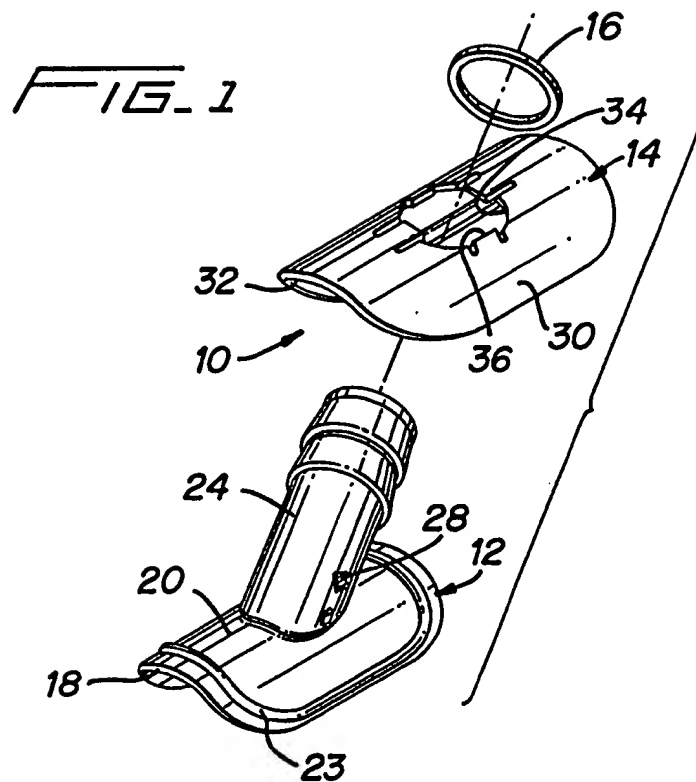
10 17. A graft attachment assembly according to any of the preceding claims, wherein the biologically compatible material is polytetrafluoroethylene.

 18. A method of attaching a graft to a first vessel comprising the steps of:

- 15 (a) placing a base portion of a graft attachment assembly within a lumen of the first vessel, the graft attachment assembly including a branch portion projecting from the base portion, the branch portion being positioned to extend from the vessel;
- (b) positioning a second vessel about a first end of the branch portion; and
- 20 (c) frictionally securing the second vessel about the branch portion.

19. A method of attaching a graft to a first vessel according to any of the preceding claims, further comprising the step of clamping the base portion of the graft attachment assembly to the first vessel.

5 20. A method of attaching a graft to a first vessel according to any of the preceding claims, further comprising the step of locking the base portion of the graft attachment assembly in the clamped position with respect to the first vessel.



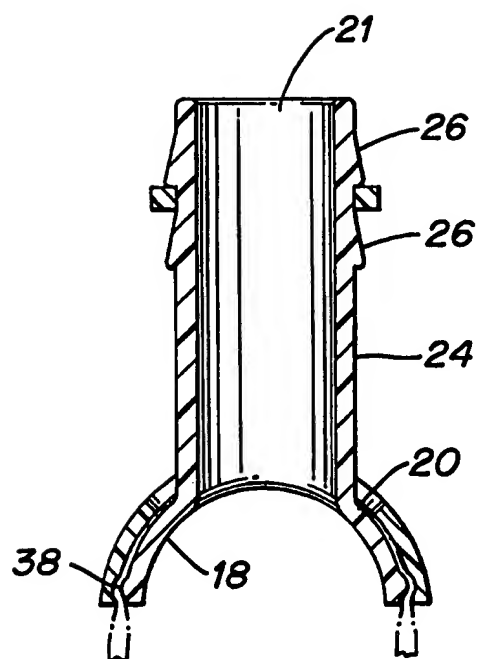
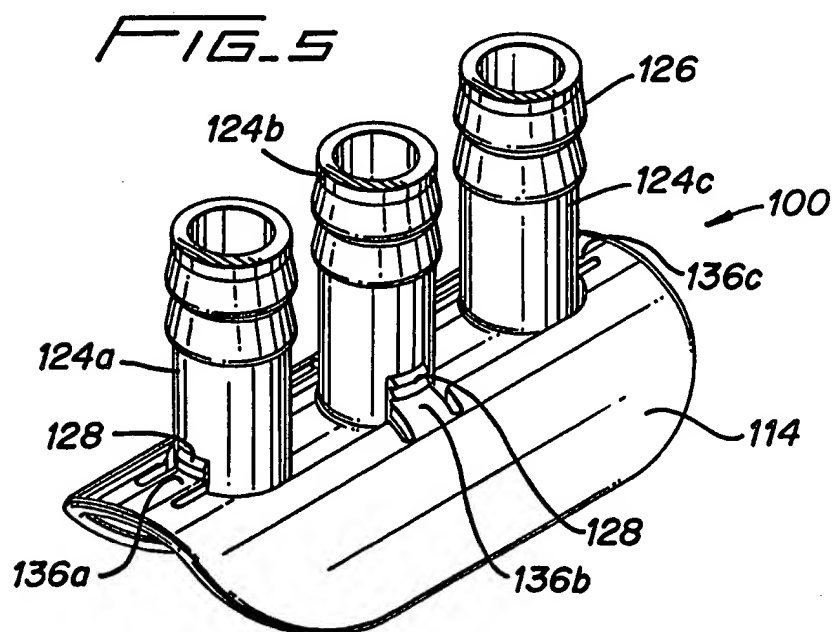
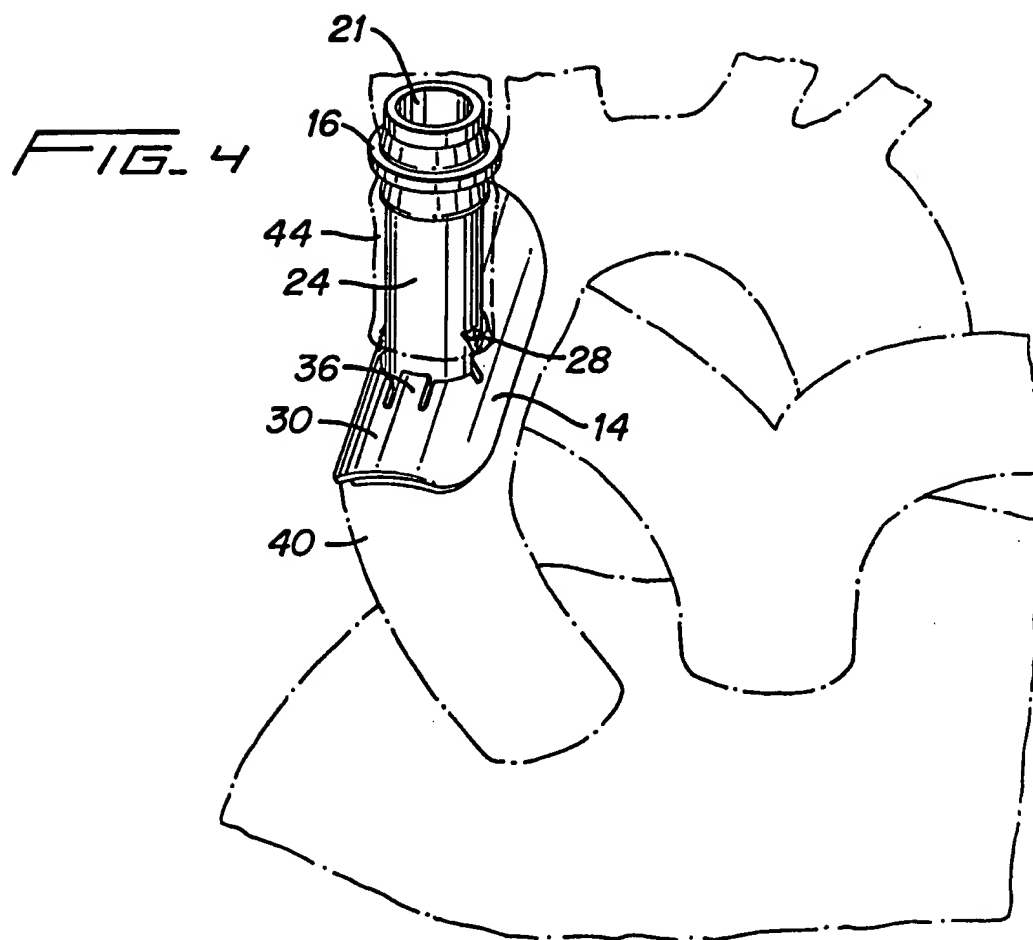


FIG. 3



INTERNATIONAL SEARCH REPORT

Intern. Application No

PCT/US 98/05031

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 82 01644 A (KASTER) 27 May 1982 see abstract; figures ---	1,3,16 9
X A	FR 1 518 083 A (H. PFAU-WANFRIED GMBH) 17 July 1968 see page 2, right-hand column, line 37 - line 58; figures 2-4 ---	1 9
A	WO 93 00868 A (OWEN) 21 January 1993 ---	
A	US 4 523 592 A (DANIEL) 18 June 1985 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

10 July 1998

Date of mailing of the international search report

29.07.98

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Smith, C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/05031

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr. Jnal Application No

PCT/US 98/05031

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8201644 A	27-05-1982	US 4366819 A AU 7891081 A CA 1175726 A EP 0064535 A	04-01-1983 07-06-1982 09-10-1984 17-11-1982
FR 1518083 A	17-07-1968	NONE	
WO 9300868 A	21-01-1993	AU 658915 B CA 2112474 A EP 0593600 A JP 7500023 T US 5456714 A	04-05-1995 21-01-1993 27-04-1994 05-01-1995 10-10-1995
US 4523592 A	18-06-1985	NONE	